

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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SARAH K. JONES,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 19-3V

Special Master Christian J. Moran

Filed: April 29, 2020

motion for ruling on the record; no
expert report

Glen H. Sturtevant, Jr., Rawls Law Group, Richmond, VA, for petitioner;
Linda S. Renzi, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Sarah Jones is seeking an award through the National Childhood Vaccine Injury Compensation Program, codified at 42 U.S.C. § 300aa–10 through 34. Ms. Jones alleged that a hepatitis B vaccination caused her to develop transverse myelitis. However, early in the case, Ms. Jones conceded that she was unable to find an expert willing to offer a supportive opinion. Considering the absence of an expert report along with the record as a whole, the undersigned finds that Ms. Jones has not carried her burden and is not entitled to compensation.

¹ Because this decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the decision will be available to anyone with access to the internet (<http://www.cofc.uscourts.gov/aggregator/sources/7>). In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material before posting the decision.

I. Facts

Sarah Jones was born on April 21, 1968. Exhibit 8. Ms. Jones received multiple vaccinations on March 15, 2017: hepatitis A, hepatitis B, yellow fever, and typhoid. Exhibit 8 at 1-2, 4-7. She attested that 15 days later she began to feel unwell, run-down, and tired. Exhibit 1 (Affidavit) at 1. Reported months later at a medical appointment, Ms. Smith stated that she suffered a flu-like illness in early April after receiving these vaccinations. Exhibit 6 at 17 (patient's subjective history at July 5, 2017 hospital admission). On April 24, 2017, Ms. Jones received the second dose of the hepatitis B vaccine. Exhibit 6 at 17.

In her affidavit, Ms. Jones estimated that she began to experience tingling in her legs in mid-May 2017. Exhibit 1 at 1. At medical appointments seeking treatment, Ms. Jones reported that the tingling began on approximately May 24, 2017, (exhibit 5 at 14-16 – June 14, 2017 appointment), May 27, 2017, (exhibit 5 at 17-19 – June 8, 2017 appointment) and late-May 2017 (exhibit 6 at 17).

For the second half of June 2017, Ms. Jones traveled to Malawi. While abroad, she stated that her gait was off. Exhibit 6 at 17. On July 5, 2017, she went to the emergency room complaining of numbness and tingling and was admitted for care. Id. at 10. Three days later, she was discharged with a diagnosis of transverse myelitis. Id. at 16. At a later appointment in a neurology department, a nurse practitioner noted that Ms. Jones potentially had transverse myelitis. Exhibit 9 at 3.

With her symptoms becoming worse, Ms. Jones was admitted to UNC Healthcare on August 24, 2017. Exhibit 11 at 5. Early in her hospital stay, Ms. Jones was seen by neurologist Veenka Veerappan who included transverse myelitis in the differential diagnosis while also noting from a literature review that transverse myelitis has been associated with the hepatitis B, typhoid, and yellow fever vaccines. Id. at 186. Before Ms. Jones's discharge on September 8, 2017, she received a transverse myelitis diagnosis. Id. at 5-17, 27.

Later in 2017, Ms. Jones was seen by neurologist Carlos Pardo-Villamizar. Dr. Pardo-Villamizar assessed Ms. Jones as having an acute myelopathic syndrome that appeared to be temporally related to a yellow fever vaccination. Exhibit 13 at 13. Into 2018, even after Ms. Jones had participated in physical therapy, she had limited ability to ambulate independently. Exhibit 15. Ms. Jones has not submitted any more recent records to indicate her current status.

II. Procedural History

Ms. Jones alleged that the hepatitis A and B vaccines that she received on March 15, 2017, caused her to develop transverse myelitis and, in the alternative, alleged that the vaccines significantly aggravated an underlying disorder that resulted in transverse myelitis. Pet., filed Jan. 2, 2019, at 1. Soon after on January 18, 2019, Ms. Jones filed her outstanding medical records and a statement of completion.

While waiting for the Secretary to review the medical records for completeness, Ms. Jones filed a status report to highlight any instances in the medical records where a doctor attributed her injuries to a vaccination. Pet'r's Status Rep., filed May 20, 2019. Ms. Jones highlighted several instances where a doctor identified the yellow fever vaccination as the cause of her transverse myelitis and a few instances where the doctor generically referenced "vaccination" as the cause. Ms. Jones argued that, while the doctors were attributing causation to the rarely administered yellow fever vaccination, the doctors could have also attributed causation to the hepatitis B vaccination. Because these medical record citations did not clearly support Ms. Jones's claimed connection between the hepatitis A or B vaccinations and her transverse myelitis, she was encouraged to consider retaining an expert. Order, issued May 30, 2019.

On July 1, 2019, Ms. Jones advised that she will pursue retaining an expert before the Secretary filed his Rule 4 report. Subsequently, instructions to guide the submission of expert reports were issued. Order, issued Sept. 6, 2019.

On November 7, 2019, Ms. Jones filed a status report stating that "due to the complex nature of the medical condition which forms the basis of her vaccine injury claim, [she] has been unsuccessful in retaining a suitable expert in this matter." At the next status conference on November 25, 2019, Ms. Jones stated that she was unable to retain an expert and would be filing a motion for ruling on the record. A schedule for briefing was then set. Order, issued Nov. 26, 2019.

On January 16, 2020, Ms. Jones filed a motion for ruling on the record and a memorandum in support. Ms. Jones refined her claim to only allege that the hepatitis B vaccine caused her transverse myelitis. Pet'r's Mot. at 1. She again noted that she was unable to find a medical expert willing to provide a supportive opinion. *Id.* Despite the lack of an expert opinion, Ms. Jones argued that persuasive medical literature and "the precedential history of petitioners who have prevailed in such cases" weighed in favor of compensation. Pet'r's Mem. at 5.

Ms. Jones asserted that the onset of her transverse myelitis symptoms occurred within one month of the vaccination. Id. at 8.

On March 20, 2020, the Secretary filed a response to the motion combined with his standard Rule 4 report. In regard to the medical literature filed by Ms. Jones, the Secretary stated that none of the articles offered evidence of a causal connection between the hepatitis B vaccine and transverse myelitis. Resp't's Resp. at 8. Considering the lack of an expert opinion and the nature of the medical literature, the Secretary asserted that Ms. Jones had not established a medical theory under Althen prong one. Connectedly, the Secretary seemed to imply that the absence of a medical theory necessarily undermined Ms. Jones's ability to establish Althen prong two, a logical sequence of cause and effect. Id. at 8-9. As for Althen prong three, the Secretary stated that Ms. Jones's 62-day onset of transverse myelitis on May 16, 2017, was not established as a medically appropriate time frame.

On March 27, 2020, Ms. Jones filed a reply. She reiterated her argument that the medical literature submitted along with the vaccine cases cited were sufficient to establish the Althen prongs. Ms. Jones noted that respondent did not cite any medical literature to rebut her own. As for the onset of symptoms, Ms. Jones cited her affidavit as evidence that her symptoms began before the Secretary's stated 62-day onset.

This matter is now ready for adjudication.

III. Standards for Adjudication

Before a hearing is held, either party can move for a ruling on the record. Smith v. Sec'y of Health & Human Servs., No. 14-982V, 2017 WL 2927419, at *1 (Fed. Cl. Spec. Mstr. June 2, 2017) (motion by respondent); Goins v. Sec'y of Health & Human Servs., No. 15-848V, 2017 WL 1231687, at *2 (Fed. Cl. Spec. Mstr. Mar. 10, 2017) (motion by petitioner). The Federal Circuit affirmed that 42 U.S.C. § 300aa—12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)) gives special masters the discretion to either hold an evidentiary hearing or to decide the case on the written record. Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020) (holding that a special master did not abuse his discretion by deciding a case without holding an evidentiary hearing since the record was fully developed).

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence.” Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

For an off-Table vaccine claim, petitioners bear a burden “to show by preponderant evidence that the vaccination brought about [the vaccinee’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

A. For Althen prong one, petitioner presented insufficient evidence to meet her burden by relying on non-binding precedent and medical literature.

In deciding issues, special masters consider the record as a whole. 42 U.S.C § 300aa—13(a). When looking at the record as a whole, special masters may draw upon their accumulated expertise. Whitecotton v. Sec’y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (quoting Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)). This wisdom includes adjudications by other judicial officers.

Adjudications on different questions carry different levels of importance. On questions of law, the Federal Circuit establishes the binding interpretation.

But, on questions of fact, an adjudication, even a statement from the Federal Circuit, is not binding. See Bean-Sasser v. Sec’y of Health & Human Servs., No. 127 Fed. Cl. 161, 167 (2016), denying mot. for rev., No. 13-326V, 2016 WL 1649355 (Fed. Cl. Spec. Mstr. Apr. 5, 2016). The Court ruled that the special master was not arbitrary in determining that the Federal Circuit’s opinion in Capizzano, which upheld the plausibility of a causal relationship between the hepatitis B vaccine and rheumatoid arthritis, did not require a finding that the

hepatitis B vaccine can cause rheumatoid arthritis in every case. Id. (citing Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006)).

Questions of causation turn on the evidence presented, and reasonable special masters may weigh evidence differently. Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000); Estep v. Sec'y of Health & Human Servs., 28 Fed. Cl. 664, 669 (1993). Compared with earlier cases, the parties may present new or different evidence on the same combination of vaccine and alleged injury, leading to a different outcome. See Novartis AG v. Noven Pharm. Inc., 853 F.3d 1289, 1293 (Fed. Cir. 2017) (noting that a ruling from the Delaware district court about a patent did not bind the Patent Trial and Appeal Board in a consideration about the same patent). These reasons contribute to the principle that special masters' adjudications do not dictate outcome in other cases. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019).

Nevertheless, here, Ms. Jones argues she has met her burden with regard to Althen prong one by citing prior rulings from special masters, including Mosley v. Sec'y of Health & Human Servs., No. 08-724V, 2015 WL 2354316 (Fed. Cl. Spec. Mstr. Apr. 27, 2015) and Pecorella v. Sec'y of Health & Human Servs., No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. Sept. 17, 2008). The undersigned declines to follow those cases for two main reasons.

First, the evidence in this case is different. The primary difference is that the petitioners in those cases retained experts. Ms. Jones does not. While Ms. Jones has submitted some articles (exhibits 17-19), the submission of literature by itself does not substitute for a doctor's statement. See 42 U.S.C. § 300aa—13 (allowing special masters to find causation based upon "medical record or medical opinion").

Second, the adjudicatory standard requires Ms. Jones to establish a medical theory by a preponderance of the evidence. Ms. Jones acknowledges the preponderance standard. Pet'r's Mem. at 9. However, the cases cited by Ms. Jones rely on the lesser standard of biological plausibility that has been discredited by the Federal Circuit. Moberly, 592 F.3d at 1322 ("a 'plausible' or 'possible' causal link between the vaccine and the injury, [] is not the statutory standard"); see Mosley, 2015 WL 2354316, at *16 (a Tdap-transverse myelitis ruling that relies on three cases that either use the biological plausibility standard or have a de

minimus discussion of prong one²); Pecorella, 2008 WL 4447607, at *4 (finding that petitioner's medical theories satisfied Althen prong one because they were biologically plausible). For both reasons, the undersigned declines to follow the cases cited by Ms. Jones.

Aside from her citation of two prior cases, Ms. Jones also submitted three medical articles in support of her medical theory. Exhibits 17-19. When citing these articles, Ms. Jones only provided a single-sentence quotation from each article without any further discussion or explanation by an expert. Pet'r's Mem. at 6. Respondent does not discuss any of the articles and merely concludes that the articles do not support vaccine causation. Resp't's Resp. at 8. The question of how much weight to assign to medical literature is a factual one based on whether an expert has provided an interpretation of the literature and whether, absent an expert's assistance, a special master can interpret the literature. Moriarty v. Sec'y of Health and Human Servs., 844 F.3d 1322, 1330 (Fed. Cir. 2016). Before addressing the undersigned's ability to interpret Ms. Jones's literature, an even more basic and important question is: what medical theory has Ms. Jones proposed? Neither Ms. Jones's motion nor her memorandum contains any articulation of a medical theory connecting the hepatitis B vaccine to transverse myelitis. Ms. Jones "must provide a reputable medical or scientific explanation that pertains specifically to [her] case." Moberly, 592 F.3d at 1322. In citing the other vaccine cases, Ms. Jones has only pointed to their conclusion of vaccine causation and has not imported, or even described, the medical theories in those cases. Therefore, without a medical theory, the literature carries little weight.

Thus, considering the absence of a medical theory, cited cases that are not being followed for the reasons stated above, and medical literature submitted without context, the undersigned finds that Ms. Jones has not established Althen prong one by a preponderance of the evidence.

² Initially, despite being a Tdap-transverse myelitis case, Mosely may have some relevance to this hepatitis B-transverse myelitis case, Ms. Jones has not explained how the two vaccines are similar or how they could cause the same disease. As for the underlying Tdap-transverse myelitis cases, Mosely cites Roberts v. Sec'y of Health & Human Servs., No. 09-427V, 2013 WL 5314698, at *6-7 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (special master found that petitioner had a "plausible" medical theory), Helman v. Sec'y of Health & Human Servs., No. 10-813V, 2012 WL 1607142, at *3 (Fed. Cl. Spec. Mstr. Apr. 5, 2012) (the entire medical theory section is only two sentences long), and Bowes v. Sec'y of Health & Human Servs., No. 01-481V, 2006 WL 2849816, at *5 (Fed. Cl. Spec. Mstr. Sept. 8, 2006) (ruling relies on Pafford v. Sec'y of Health & Human Servs., 64 Fed. Cl. 19, 27-31 (2005), aff'd 451 F.3d 1352 (Fed. Cir. 2006), which states that a medical theory need only be plausible).

B. For Althen prong 3, petitioner erroneously relies solely upon prior adjudications and lacks a required opinion regarding onset.

The timing prong actually contains two parts. A petitioner must show the “timeframe for which it is medically acceptable to infer causation” and the onset of the disease occurred in this period. Shapiro v. Sec’y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff’d without op., 503 F. App’x 952 (Fed. Cir. 2013).

For the expected medical interval, Ms. Jones relies on previous adjudications in which one special master found 60 days appropriate. Pet’r’s Mem. at 8; Pet’r’s Reply at 3. However, for reasons explained above, this argument is not persuasive.

Moreover and more importantly, even if the evidence established that 60 days is an appropriate interval, onset is not clear. Ms. Jones asserted that she experienced the onset of transverse myelitis symptoms within one month of the vaccination. Pet’r’s Mem. at 8, citing exhibit 1 (affidavit) at 1. In the affidavit, she describes flu-like symptoms on March 31, 2017; a sharp, stabbing pain in her back after turning her torso on April 25, 2017; and tingling, restlessness, and numbness in her legs in mid-May 2017. Exhibit 1 at 1. In her brief, Ms. Jones has not specifically stated which initial symptom she believes is related to transverse myelitis. See Pet’r’s Mem. at 8.

The Secretary stated that the onset of transverse myelitis symptoms was 62 days. Resp’t’s Resp. at 9. The Secretary did not cite any medical records for this statement or specify the symptoms that indicate an onset of transverse myelitis.

Medical records suggest that the onset of neurologic symptoms might be later in May or early June 2017. Exhibit 5 at 17-19 (June 8, 2017 appointment complaining of tingling in feet and legs with the onset of foot pain one week prior), 14-16 (June 14, 2017 appointment reporting that tingling from feet to back began three weeks prior); exhibit 6 at 17 (“In late May, she began noticing symmetric areas of aching/tingling over the MTP joints of her feet.”), 10 (July 5, 2017 ER visit where Ms. Jones reported numbness and tingling in her legs for one month); exhibit 11 at 19 (noting that neurologic symptoms developed less than 6 weeks after vaccination).

Ms. Jones could have benefited from an opinion regarding onset to interpret the medical records and state which symptoms were indicative of transverse myelitis. Without this opinion, she fails to meet her burden of proof on Althen prong 3.

C. For Althen prong 2, P has failed to meet her burden of proof.

Given that Ms. Jones did not present a persuasive medical theory explaining how hepatitis B vaccine can cause transverse myelitis and given that P did not establish that her transverse myelitis arose in a time suggestive of causation, it also follows as a matter of logic that Ms. Jones has not presented a logical sequence of cause and effect. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012). However, this element is discussed further for the sake of completeness.

As Ms. Jones acknowledged, her receipt of vaccines that the Secretary has not listed in the Table complicates her case. See Goring v. Sec'y of Health & Human Servs., No. 16-1458V, 2019 WL 3938705, at *16-21 (Fed. Cl. Spec. Mstr. May 6, 2019). This issue is especially thorny because most of Ms. Jones's treating doctors associated her neurologic problems with vaccines other than the covered vaccine, notably the yellow fever vaccine. See exhibit 6 at 62 ("I suspect that the patient had an infectious myelitis related to Yellow Fever vaccination (as she also had symptoms of yellow fever per her) and this was a monophasic illness."), 79 ("There is one case report in the literature about myelitis following a fever vaccination."), 90 ("Ultimately suspected to be infection myelitis related to Yellow Fever Vaccination."); exhibit 11 at 42 ("Another possibility is that her transverse myelitis is a complication from yellow fever vaccine due to the timing of administration and her symptoms."); exhibit 13 at 18 ("We suspect that the yellow fever vaccination was the trigger for her myelitis.").

While Ms. Jones did not identify any statements by treating doctors associating the hepatitis B vaccine with her transverse myelitis, the Secretary noted that a neurologist, Dr. Veenka Veerappan, pointed out that transverse myelitis has been associated with the hepatitis B, typhoid, and yellow fever vaccines based on a medical literature review. Resp't's Resp. at 5 (citing exhibit 11 at 19). Dr. Veerappan did not appear to single out one of the vaccines as causative or to make any conclusions about the etiology of Ms. Jones's condition.

As for all the other statements from her treating doctors, Ms. Jones's only argument against these statements is that the rarity of the yellow fever vaccine

somehow blinded the doctors to the other vaccines administered at the same time resulting in the omission of any references to the hepatitis B vaccine. Treating doctors are entitled to deference because they “are likely to be in the best position to determine” a logical sequence of cause and effect. Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Ms. Jones has not presented any reason to doubt the accuracy of these medical records. She could have obtained statements from these treating doctors to clarify whether the hepatitis B vaccine could also have been causative, but she did not do so. Alternatively, she could have benefited from an opinion from a retained expert. But, her efforts to obtain such a statement were not successful. See Pet’r’s Mot. ¶ 2.

Thus, absent a medical theory to pair with a logical sequence, with possible support from one treating doctor for her alleged vaccine causation, and with statements from many other treating doctors in support of a non-covered vaccine causation (yellow fever vaccine – transverse myelitis), the undersigned finds that Ms. Jones has not established Althen prong two.

V. Conclusion

As Ms. Jones describes, the transverse myelitis has turned her life upside down and she merits admiration for the challenges she has overcome. However, special masters cannot award compensation based upon sympathy. Here, the evidence does not support a finding of causation. Therefore, Ms. Jones is not entitled to compensation.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master